

**IN THE UNITED STATES DISTRICT COURT FOR THE  
DISTRICT OF NEW JERSEY**

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IN RE: JOHNSON & JOHNSON	)	
TALCUM POWDER PRODUCTS	)	
MARKETING, SALES PRACTICES AND	)	MDL Docket No. 2738
PRODUCTS LIABILITY LITIGATION	)	

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This Document Relates To All Cases

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**DEFENDANTS JOHNSON & JOHNSON AND LLT MANAGEMENT,  
LLC'S MEMORANDUM OF LAW IN SUPPORT OF MOTION TO  
EXCLUDE THE OPINIONS OF DR. JOHN GODLESKI**

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## **TABLE OF CONTENTS**

	<b><u>Page</u></b>
FACTUAL BACKGROUND .....	2
ARGUMENT.....	9
I. DR. GODLESKI’S OPINION THAT THE MERE PRESENCE OF TALC PARTICLES IN A PLAINTIFF’S TISSUE SUPPORTS A FINDING OF SPECIFIC CAUSATION IS UNSUPPORTED AND UNRELIABLE. ....	9
II. DR. GODLESKI’S OPINIONS ARE INADMISSIBLE BECAUSE THEY CANNOT BE TIED TO ANY PLAINTIFF’S THEORY OF HARM.....	18
CONCLUSION .....	20

## TABLE OF AUTHORITIES

### Page(s)

### CASES

<i>In re Accutane Products Liability</i> , MDL No. 1626, 2009 U.S. Dist. LEXIS 77662 (M.D. Fla. Aug. 11, 2009).....	12
<i>In re Acetaminophen - ASD-ADHD Products Liability Litigation</i> , MDL No. 3043, 2023 U.S. Dist. LEXIS 224899 (S.D.N.Y. Dec. 18, 2023).....	12
<i>Allgood v. General Motors Corp.</i> , No. 02-1077, 2006 WL 2669337 (S.D. Ind. Sept. 18, 2006).....	15
<i>Bowers v. National Collegiate Athletic Association</i> , 564 F. Supp. 2d 322 (D.N.J. 2008).....	11
<i>Burgad v. Jack L. Marcus, Inc.</i> , 345 F. Supp. 2d 1036 (D.N.D. 2004) .....	10
<i>Buzzerd v. Flagship Carwash of Port St. Lucie, Inc.</i> , 397 F. App'x 797 (3d Cir. 2010).....	13, 20
<i>In re Diet Drugs</i> , MDL No. 1203, 2001 WL 454586 (E.D. Pa. Feb. 1, 2001).....	11
<i>Elcock v. Kmart Corp.</i> , 233 F.3d 734 (3d Cir. 2000).....	20
<i>General Electric Co. v. Joiner</i> , 522 U.S. 136 (1997).....	11
<i>In re Human Tissue Products Liability Litigation</i> , 582 F. Supp. 2d 644 (D.N.J. 2008).....	10

<i>Lloyd v. Johnson &amp; Johnson (Plaintiff Eva Echeverria only),</i> No. BC628228, 2017 WL 4325958 (Cal. Super. Ct. July 18, 2017).....	1, 10, 12
<i>Magistrini v. One Hour Martinizing Dry Cleaning,</i> 180 F. Supp. 2d 584 (D.N.J. 2002).....	17
<i>In re Onglyza (Saxagliptin) &amp; Kombiglyze (Saxagliptin &amp; Metformin)</i> <i>Products Liability Litigation,</i> 93 F.4th 339 (6th Cir. 2024).....	12
<i>In re Pella Corp. Architect &amp; Designer Series Windows Marketing, Sales</i> <i>Practices &amp; Products Liability Litigation,</i> 214 F. Supp. 3d 478 (D.S.C. 2016).....	15
<i>Pluck v. BP Oil Pipeline Co.,</i> 640 F.3d 671 (6th Cir. 2011).....	10
<i>Soldo v. Sandoz Pharmaceuticals Corp.,</i> 244 F. Supp. 2d 434 (W.D. Pa. 2003) .....	11, 17
<i>Wade-Greaux v. Whitehall Laboratories, Inc.,</i> 874 F. Supp. 1441 (D.V.I. 1994).....	11, 14

## RULE

Fed. R. Evid. 702 .....	9
-------------------------	---

## OTHER AUTHORITIES

Cramer, <i>Presence of Talc in Pelvic Lymph Nodes of a Woman with Ovarian</i> <i>Cancer and Long-Term Genital Exposure to Cosmetic Talc</i> , 110(2) Obstet. Gynecol. 498 (2007).....	12
Heller, <i>The Relationship Between Perineal Cosmetic Talc Usage and</i> <i>Ovarian Talc Particle Burden</i> , 174(5) Obstet. Gynecol. 1507 (1996) .....	19
McDonald, <i>Migration of Talc From the Perineum to Multiple Pelvic Organ</i> <i>Sites: Five Case Studies With Correlative Light and Scanning</i> <i>Electron Microscopy</i> , 152 Am. J. Clin. Pathol. 590 (2019) .....	12

Dr. John Godleski, a pulmonary pathologist, seeks to testify that the alleged presence of a few particles that he claims are consistent with talc in tissue samples taken from the ovaries, fallopian tubes and other pelvic tissue of five of the six bellwether plaintiffs demonstrates a “causal link” between their talc exposure and ovarian cancers. Dr. Godleski’s opinions are inadmissible because they are not based on any reliable methodology and are instead pure *ipse dixit*. See *Lloyd v. Johnson & Johnson (Plaintiff Eva Echeverria only)*, No. BC628228, 2017 WL 4325958, at \*9 (Cal. Super. Ct. July 18, 2017) (trial order) (noting that Dr. Godleski “provides absolutely no explanation as to how he reached th[e] conclusion” that particles in a plaintiff’s tissue are “contributory evidence for a causal link between the presence of talc and the development of this patient’s ovarian cancer”).<sup>1</sup>

**First**, Dr. Godleski has no scientific support for the notion that the presence in a patient’s tissue of “birefringent material seen in talc” is capable of causing the varying subtypes of ovarian cancer with which the plaintiffs at issue have been diagnosed.<sup>2</sup> In addition, Dr. Godleski’s assertion that the various plaintiffs’ ovaries must contain “significant amounts of talc” based on purportedly observing

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<sup>1</sup> Judge Wolfson’s *Daubert* ruling did not address Dr. Godleski’s opinions.

<sup>2</sup> (See Dep. of John Godleski (“3/28/24 Godleski Dep.”) 52:22-53:2, Mar. 28, 2024 (Ex. 1 to Decl. of Jessica Davidson (“Davidson Decl.”))).

a few particles that he claims are consistent with talc in a limited number of tissue samples is highly speculative, unscientific and unreliable. This is all the more true because Dr. Godleski ignores the other foreign materials he identified in each plaintiff's tissue samples and fails to consider whether those materials could have caused each plaintiff's cancer.

*Second*, Dr. Godleski has no basis to conclude that the particles he purports to have found are attributable to perineal talc use at all, much less the perineal use of talcum powder manufactured by defendants, rendering his findings irrelevant and unreliable.

For all of these reasons, discussed further below, Dr. Godleski's opinions should be excluded.

### **FACTUAL BACKGROUND**

Dr. Godleski is a pulmonary pathologist who has focused his career on respiratory disease.<sup>3</sup> As Dr. Godleski has conceded in other talc cases, he is not a gynecological pathologist, and his background does not include determining the

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<sup>3</sup> (See generally CV of John Godleski (Ex. 2 to Davidson Decl.); see also Dep. of John Godleski ("4/19/24 Godleski Dep.") 17:21-23, Apr. 19, 2024 (Ex. 3 to Davidson Decl.).)

causes of ovarian cancer.<sup>4</sup> Nevertheless, based on his review of an “extremely small volume” of tissue taken from the ovaries, fallopian tubes and other pelvic areas of bellwether plaintiffs Hilary Converse, Anna Gallardo, Carter Judkins, Tamara Newsome and Pasqualina Rausa, Dr. Godleski seeks to opine that “significant amount[s] of talc” were present in the pelvic tissue of these five plaintiffs, providing “contributory evidence for a causal link between the presence of [talc] and the development of” these plaintiffs’ ovarian cancers.<sup>5</sup>

According to Dr. Godleski, his protocol for analyzing the plaintiffs’ tissue samples in this case has not changed from the work he has done in other talc litigation.<sup>6</sup> Specifically, Dr. Godleski used a method known as polarized light microscopy to detect birefringent foreign material in each of the relevant plaintiffs’ tissue samples.<sup>7</sup> Dr. Godleski then reviewed the slides using scanning electron

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<sup>4</sup> (4/19/24 Godleski Dep. 17:21-23; *see also* Dep. of John Godleski (“5/27/15 Godleski *Blaes* Dep.”) 30:2-5, 34:16-18, *Blaes v. Johnson & Johnson*, No. 4:14-cv-00213-RLW (E.D. Mo. May 27, 2015) (Ex. 4 to Davidson Decl.).)

<sup>5</sup> (*See* Rep. of John Godleski Re: Anna Gallardo (“Godleski *Gallardo* Rep.”) at 6, 8, July 21, 2021 (Ex. 5 to Davidson Decl.); Rep. of John Godleski Re: Hilary Converse (“Godleski *Converse* Rep.”) at 4, 5-6, July 12, 2021 (Ex. 6 to Davidson Decl.); Rep. of John Godleski Re: Tamara Newsome (“Godleski *Newsome* Rep.”) at 4, 7, June 24, 2021 (Ex. 7 to Davidson Decl.); Rep. of John Godleski Re: Pasqualina Rausa (“Godleski *Rausa* Rep.”) at 4, 5-6, June 21, 2021 (Ex. 8 to Davidson Decl.); Rep. of John Godleski Re: Carter Judkins (“Godleski *Judkins* Rep.”) at 4, 5, June 18, 2021 (Ex. 9 to Davidson Decl.).)

<sup>6</sup> (*E.g.*, 3/28/24 Godleski Dep. 176:8-17.)

<sup>7</sup> (*E.g.*, Godleski *Converse* Rep. at 2.)

microscopy and energy dispersive X-ray analyses to observe the foreign material and identify any particles that he believed were talc.<sup>8</sup> The only methodology that Dr. Godleski relied upon to identify particles as talc was to look at particles that had magnesium and silicon in the accepted energy dispersive X-ray system spectral proportions for talc.<sup>9</sup> Specifically, he identified as talc any particle that had magnesium and silicon atomic weight percentage ratios “all within + 5% of the accepted Mg/Si atomic weight % ratio of 0.649 for talc.”<sup>10</sup> He admitted, however, that he cannot be certain whether the birefringent particulate matter he identified as being consistent with talc was not some other substance.<sup>11</sup>

For each plaintiff at issue, Dr. Godleski first identified the slides that he believed showed the most birefringent particulate matter and then examined the tissue blocks for those slides using scanning electron microscopy (“SEM”) technology and energy dispersive X-ray system (“EDS”).<sup>12</sup> Dr. Godleski admits that he only examined the tissue blocks that he believed were most likely to

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<sup>8</sup> (E.g., *id.* at 4.)

<sup>9</sup> (E.g., *id.*)

<sup>10</sup> (E.g., *id.*; *see also* Dep. of John Godleski (“3/29/24 Godleski Dep.”) 72:8-16, Mar. 29, 2024 (Ex. 10 to Davidson Decl.).)

<sup>11</sup> (*See* 3/28/24 Godleski Dep. 52:22-53:9 (Dr. Godleski agreeing that “[he] cannot say that birefringent material seen is talc” and conceding that “lots of particles are birefringent”).)

<sup>12</sup> (E.g., 3/28/24 Godleski Dep. 28:25-29:13, 182:12-22.)



contain foreign particles and that it was much less likely that particles were present in the tissue blocks that he chose not to examine.<sup>13</sup> Based on his examination of these subjectively selected tissue blocks, Dr. Godleski reported the following findings with respect to each plaintiff:

- ***Pasqualina Rausa*** (diagnosed with high-grade serous ovarian cancer).<sup>14</sup> Dr. Godleski reviewed 46 slides of Ms. Rausa's tissue and purports to have detected birefringent material in 25 of those slides.<sup>15</sup> A closer examination of the tissue blocks corresponding to those particular slides purportedly revealed 515 foreign particles in Ms. Rausa's tissue.<sup>16</sup> Only 2 of the 515 foreign particles (~.3%) were identified by Dr. Godleski as being within the accepted magnesium and silicon atomic weight percentage ratios applicable to talc particles.<sup>17</sup>
- ***Hilary Converse*** (diagnosed with clear cell carcinoma of the ovary).<sup>18</sup> Dr. Godleski detected birefringent material in 25 of the 45 slides of Ms. Converse's tissue that he reviewed.<sup>19</sup> A closer examination of the tissue blocks corresponding to those particular slides purportedly revealed 255 foreign particles in Ms. Converse's tissue.<sup>20</sup> Only 4 of the 255 foreign particles (~1.5%) were identified as being within the accepted magnesium and silicon atomic weight percentage ratios

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<sup>13</sup> (See *id.* 182:12-22.)

<sup>14</sup> (Godleski *Rausa* Rep. at 2.)

<sup>15</sup> (*Id.* at 3.)

<sup>16</sup> (*Id.* at 4.)

<sup>17</sup> (*Id.*)

<sup>18</sup> (Godleski *Converse* Rep. at 2.)

<sup>19</sup> (*Id.*)

<sup>20</sup> (*Id.* at 4.)

applicable to talc particles.<sup>21</sup>

- ***Carter Judkins*** (diagnosed with poorly differentiated serous carcinoma of the ovary).<sup>22</sup> Dr. Godleski detected birefringent material in 21 of the 31 slides of Ms. Judkins' tissue that he reviewed.<sup>23</sup> A closer examination of the tissue blocks corresponding to those particular slides purportedly revealed 932 foreign particles in Ms. Judkins' tissue.<sup>24</sup> Only 17 of the 932 foreign particles (~1.8%) were identified as being within the accepted magnesium and silicon atomic weight percentage ratios applicable to talc particles.<sup>25</sup>
- ***Tamara Newsome*** (diagnosed with endometrioid adenocarcinoma of the ovary).<sup>26</sup> Dr. Godleski detected birefringent material in 8 of the 31 slides of Ms. Newsome's tissue that he reviewed.<sup>27</sup> A closer examination of the tissue blocks corresponding to those particular slides purportedly revealed 821 foreign particles in Ms. Newsome's tissue.<sup>28</sup> Only 31 of the 821 foreign particles (~3.7%) were identified by Dr. Godleski as being within the accepted magnesium and silicon atomic weight percentage ratios applicable to talc particles (with only one identified as a fiber), and only one fiber fragment of the 821 foreign particles was identified by Dr. Godleski as being within the accepted range of magnesium and silicon atomic weight percentage ratio applicable to tremolite asbestos.<sup>29</sup>
- ***Anna Gallardo*** (diagnosed with poorly differentiated endometrioid

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<sup>21</sup> (*Id.*)

<sup>22</sup> (Godleski *Judkins* Rep. at 2.)

<sup>23</sup> (*Id.*)

<sup>24</sup> (*Id.* at 4.)

<sup>25</sup> (*Id.* at 3-4.)

<sup>26</sup> (Godleski *Newsome* Rep. at 2.)

<sup>27</sup> (*Id.*)

<sup>28</sup> (*Id.* at 4.)

<sup>29</sup> (*Id.* at 3-4.)

adenocarcinoma of the ovary).<sup>30</sup> Dr. Godleski detected birefringent material in 25 of the 50 slides of Ms. Gallardo's tissue that he reviewed.<sup>31</sup> A closer examination of the tissue blocks corresponding to those particular slides purportedly revealed 795 foreign particles in Ms. Gallardo's tissue.<sup>32</sup> 208 of the 795 foreign particles (~26%) were identified by Dr. Godleski as being within the accepted magnesium and silicon atomic weight percentage ratios applicable to talc particles (with 15 of those identified as talc fibers), and 30 of the 795 foreign particles were identified by Dr. Godleski as being consistent with the accepted magnesium and silicon atomic weight percentage ratios applicable to tremolite asbestos fragments (only one of which was identified as a fiber).<sup>33</sup>

Dr. Godleski then extrapolated the amount of particles purportedly consistent with the accepted magnesium and silicon atomic weight percentage ratios applicable to talc that he found in these small, subjectively selected slivers of tissue to reach his ultimate conclusion that there was significant talc in the respective plaintiffs' pelvic tissue generally.<sup>34</sup> Dr. Godleski made no attempt to identify the other foreign particles he identified in the plaintiffs' tissue samples—which make up the vast majority of the foreign material observed—much less to

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<sup>30</sup> (Godleski *Gallardo* Rep. at 2.)

<sup>31</sup> (*Id.* at 3.)

<sup>32</sup> (*Id.* at 5.)

<sup>33</sup> (*Id.* at 5-6.)

<sup>34</sup> (See, e.g., Godleski *Rausa* Rep. at 4; see also 3/29/24 Godleski Dep. 84:1-7.) Dr. Godleski applied this same methodology to extrapolate that the alleged presence of particles purportedly consistent with tremolite asbestos in certain plaintiffs' slides was evidence of a larger amount of tremolite asbestos in the tissue of those plaintiffs generally. (See 3/28/24 Godleski Dep. 115:2-10.)

rule them out as possible causes of the plaintiffs' ovarian cancers.

Dr. Godleski offers a nearly identical opinion for each plaintiff: that the mere alleged presence of talc in her pelvic tissue is evidence of a "causal link" between her alleged talc exposure and her development of ovarian cancer, regardless of the amount of talc or the specific subtype of her ovarian cancer.<sup>35</sup> Dr. Godleski conceded that he is not aware of "any studies that have been done that have correlated the risk of [each plaintiff's specific subtype of ovarian cancer] with the number of particles found in reproductive tract tissue."<sup>36</sup> Dr. Godleski also admits that, in forming these opinions, he did not take into account any information regarding each plaintiff's alleged use of talcum powder products.<sup>37</sup> Dr. Godleski also concedes that he cannot say whether the particles purportedly found in the plaintiffs' tissue samples that he identified as being consistent with talc came from Johnson's Baby Powder or Shower to Shower or some other source.<sup>38</sup>

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<sup>35</sup> (Godleski *Gallardo* Rep. at 8; Godleski *Newsome* Rep. at 7; Godleski *Converse* Rep. at 6; Godleski *Rausa* Rep. at 5-6; Godleski *Judkins* Rep. at 5.)

<sup>36</sup> (3/28/24 Godleski Dep. 223:13-21 (discussing serous carcinoma); *see also* 3/29/24 Godleski Dep 87:13-17 ("Q. Are you aware of any studies that correlated the number of talcum powder – talc particles found in tissue to the risk of developing clear-cell carcinoma? A. No. No.").)

<sup>37</sup> (*See, e.g.*, 3/29/24 Godleski Dep. 77:20-78:1.)

<sup>38</sup> (*See, e.g., id.* 81:23-82:6.)

## **ARGUMENT**

The standard for the admissibility of expert evidence under Amended Fed.

R. Evid. 702 is set forth in Defendants' General Causation *Daubert* brief and incorporated herein. Dr. Godleski's opinions do not satisfy these standards.

**I. DR. GODLESKI'S OPINION THAT THE MERE PRESENCE OF TALC PARTICLES IN A PLAINTIFF'S TISSUE SUPPORTS A FINDING OF SPECIFIC CAUSATION IS UNSUPPORTED AND UNRELIABLE.**

Dr. Godleski seeks to testify that his purported observation of any amount of particles that he identified as consistent with talc—or, with respect to plaintiffs Converse and Gallardo, any purported asbestos—in the relevant plaintiffs' tissue samples is “contributory evidence for a causal link between the presence of talc and the development of” each plaintiff's different subtype of ovarian cancer.<sup>39</sup> This opinion is inherently unreliable because it is based on a variety of speculative assumptions, is not supported by reliable science, and is undermined by Dr. Godleski's own finding of copious other foreign particles in the plaintiffs' tissue.

*First*, the key premise underlying Dr. Godleski's opinions—that the presence of any amount of particles in a patient's tissue that are identified as being consistent with talc is evidence of a causal link between their alleged talc use and

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<sup>39</sup> (See Godleski *Gallardo* Rep. at 8; Godleski *Newsome* Rep. at 7; Godleski *Converse* Rep. at 6; Godleski *Rausa* Rep. at 5-6; Godleski *Judkins* Rep. at 5.)

development of ovarian cancer—is not scientifically supported. As courts have noted, “it is well-settled that the mere existence of a toxin in the environment is insufficient to establish causation without proof that the level of exposure could cause the plaintiff’s symptoms.” *Pluck v. BP Oil Pipeline Co.*, 640 F.3d 671, 679 (6th Cir. 2011); *see also Burgad v. Jack L. Marcus, Inc.*, 345 F. Supp. 2d 1036, 1042 (D.N.D. 2004) (“The mere presence of chemicals . . . is not sufficient, by itself, to establish liability or causation in a products liability action.”). Indeed, Dr. Godleski conceded at his deposition that “the mere fact that you find a particle of material next to or attached to a tumor does not automatically mean that the particle caused the tumor,”<sup>40</sup> and there “is no literature that correlates the number of talc particles found in tissue with ovarian cancer risk.”<sup>41</sup> This alone requires exclusion of his opinions. *See In re Human Tissue Prods. Liab. Litig.*, 582 F. Supp. 2d 644, 656 (D.N.J. 2008) (“If ‘there is simply too great an analytical gap between the data and the opinion offered,’ the [c]ourt may properly exclude the expert’s testimony as ‘nothing in either *Daubert* or the Federal Rules of Evidence requires a district court to admit opinion evidence that is connected to existing data

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<sup>40</sup> (See 5/27/15 Godleski *Blaes* Dep. 133:20-134:6.)

<sup>41</sup> (See 3/29/24 Godleski Dep. 81:12-16.) *See also Lloyd*, 2017 WL 4325958, at \*9 (noting, in excluding Dr. Godleski’s causation opinion, that he has conceded that “the mere presence of a substance is not enough to show it caused a disease”).

only by the *ipse dixit* of the expert.’”) (quoting *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997)); *Bowers v. Nat’l Collegiate Athletic Ass’n*, 564 F. Supp. 2d 322, 350 (D.N.J. 2008) (excluding expert causation opinion that was “based on little more than ‘subjective belief or unsupported speculation’”) (citation omitted).

At most, Dr. Godleski cites to a single case report he co-authored that discusses a finding of talc particles in the tissue of a patient with ovarian cancer.<sup>42</sup> But “[a]necdotal reports [like case reports] . . . do not constitute epidemiologic data or studies and are not considered by teratologists in studying causation.” See *Wade-Greaux v. Whitehall Lab’ys, Inc.*, 874 F. Supp. 1441, 1453 (D.V.I. 1994), *aff’d*, No. 94-7199, 1994 WL 16973481 (3d Cir. Dec. 15, 1994); see also, e.g., *In re Diet Drugs*, MDL No. 1203, 2001 WL 454586, at \*15 (E.D. Pa. Feb. 1, 2001) (excluding expert opinion on causation for reliance on case reports, which are “universally recognized as insufficient and unreliable evidence of causation”); *Soldo v. Sandoz Pharms. Corp.*, 244 F. Supp. 2d 434, 542 (W.D. Pa. 2003) (“This [c]ourt concludes that plaintiff’s experts’ reliance on anecdotal case reports to support their causation opinions is contrary to both good scientific practice and the *Daubert* case law [and] [s]uch testimony is not ‘scientific knowledge’ and will not assist the trier of fact, and the data are not of a type reasonably relied on by experts

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<sup>42</sup> (See, e.g., Godleski *Converse Rep.* at 5-6.)

in the field.”). Moreover, the authors of that case report itself expressly **disclaim** any suggestion “that a causal relationship between ovarian cancer and talc use is proven for this case or in general.”<sup>43</sup> An expert cannot “press conclusions that study authors are not willing to make.” *In re Acetaminophen - ASD-ADHD Prods. Liab. Litig.*, MDL No. 3043, 2023 U.S. Dist. LEXIS 224899, at \*99 (S.D.N.Y. Dec. 18, 2023); *see also In re Onglyza (Saxagliptin) & Kombiglyze (Saxagliptin & Metformin) Prods. Liab. Litig.*, 93 F.4th 339, 346 (6th Cir. 2024) (excluding expert who “drew ‘unauthorized conclusions from limited data—conclusions the authors of the study d[id] not make,’ betraying a “lack of scientific rigor”) (citation omitted); *In re Accutane Prods. Liab.*, MDL No. 1626, 2009 U.S. Dist. LEXIS 77662, at \*20 (M.D. Fla. Aug. 11, 2009) (“[W]hen an expert relies on the studies of others, he must not exceed the limitations the authors themselves place on the study.”). This, too, requires exclusion of Dr. Godleski’s opinions.

In any event, even if there were scientific evidence suggesting that the

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<sup>43</sup> Cramer, *Presence of Talc in Pelvic Lymph Nodes of a Woman with Ovarian Cancer and Long-Term Genital Exposure to Cosmetic Talc*, 110(2) *Obstet. Gynecol.* 498, 500 (2007) (Ex. 11 to Davidson Decl.); *see also Lloyd*, 2017 WL 4325958, at \*9 (noting that the Cramer case report expressly “disavowed claiming a causal relationship between ovarian cancer and talc use”). Dr. Godleski relies on another study by Cramer that is unreliable because it only analyzed case reports. *See McDonald, Migration of Talc From the Perineum to Multiple Pelvic Organ Sites: Five Case Studies With Correlative Light and Scanning Electron Microscopy*, 152 *Am. J. Clin. Pathol.* 590 (2019) (Ex. 12 to Davidson Decl.).



presence of talc particles in tissue is indicative of ovarian cancer generally (and there is not), Dr. Godleski fails to consider that each individual was diagnosed with a distinct subtype of ovarian cancer and did not consider that different subtypes have different risk factors and originate in different cells. (*See* Defs.’ Mem. in Supp. of Mot. to Exclude Pls.’ Experts’ General Causation Ops. at 15-16, 72-74.)

**Second**, even if Dr. Godleski could quantify some level of alleged talc particles in tissue that results in an increased risk of ovarian cancer, he has no reliable evidence that any of the plaintiffs here crossed whatever that unspecified threshold is. *Buzzerd v. Flagship Carwash of Port St. Lucie, Inc.*, 397 F. App’x 797, 800 (3d Cir. 2010) (“[S]cientific knowledge of the harmful level of exposure to a chemical, plus knowledge that the plaintiff was exposed to such quantities, are minimal facts necessary to sustain the plaintiffs’ burden in a toxic tort case.”) (citation omitted). Indeed, Dr. Godleski only claims to have found *two* particles that were consistent with talc in the tissue samples for one plaintiff, Ms. Rausa, and minimal particles in the tissue of four other plaintiffs, Ms. Converse, Ms. Gallardo, Ms. Judkins and Ms. Newsome.<sup>44</sup> Dr. Godleski purports to be able to conclude to “a reasonable degree of medical certainty” that this meager amount of particles alleged to be talc is proof of a “causal link” between talc and these plaintiffs’

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<sup>44</sup> (*See* Godleski *Rausa* Rep. at 4; Godleski *Converse* Rep. at 4; Godleski *Gallardo* Rep. at 6; Godleski *Judkins* Rep. at 3; Godleski *Newsome* Rep. at 3.)

cancers,<sup>45</sup> while simultaneously acknowledging that there is no literature that correlates the number of talc particles found to the risk of ovarian cancer.<sup>46</sup>

Dr. Godleski attempts to sidestep finding only a few supposed talc particles per plaintiff by claiming that he only examined an “extremely small volume of tissue,” and that his findings indicate that a “significant” or “very substantial” amount of talc is present within each plaintiff’s pelvic tissue more generally.<sup>47</sup> But Dr. Godleski does not cite to any literature indicating that the total volume of talc particles found in a patient’s reproductive tissue can be extrapolated from the number of alleged particles found in a sliver of such tissue. Without such support, there is no basis for Dr. Godleski to extrapolate in the way he does. *See Wade-Greaux*, 874 F. Supp. at 1485 (D.V.I.) (“Any extrapolation that is based upon speculation or speculative data can produce only a speculative, and therefore inadmissible, opinion.”).<sup>48</sup>

Dr. Godleski’s opinions are also unreliable because of the biased manner in

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<sup>45</sup> (See, e.g., Godleski *Gallardo* Rep. at 8.)

<sup>46</sup> (3/29/24 Godleski Dep. 81:12-16.)

<sup>47</sup> (See, e.g., Godleski *Rausa* Rep. at 4; Godleski *Newsome* Rep. at 4.)

<sup>48</sup> While Dr. Godleski points to a study authored by Roggli involving asbestos particles in lung tissue (see, e.g., Godleski *Rausa* Rep. at 4; see also 3/29/24 Godleski Dep. 84:1-7), he does not claim to have undertaken any analysis capable of validating the use of the Roggli study’s technique in the context of purported talc particles in ovarian tissue (see 3/28/24 Godleski Dep. 223:8-12). This, too, requires exclusion of his opinion.

which he selects which tissues to examine. As Dr. Godleski explained, he requests the blocks that he wants to review based on which ones have “the most birefringent particles” and based on the “distribution of material.”<sup>49</sup> In doing so, Dr. Godleski introduces sampling bias into his “extrapolations,” further rendering them unreliable. *See, e.g., In re Pella Corp. Architect & Designer Series Windows Mktg., Sales Pracs. & Prods. Liab. Litig.*, 214 F. Supp. 3d 478, 493 (D.S.C. 2016) (excluding expert testimony in part based on the failure to test a random sample of the products at issue; “when an expert attempts to draw conclusions about an entire population from a sample-based analysis, ‘the sample[] must be chosen using some method that assures the sample[] [is] appropriately representative of the larger entity or population being measured’”) (citation omitted); *Allgood v. Gen. Motors Corp.*, No. 02-1077, 2006 WL 2669337, at \*11 (S.D. Ind. Sept. 18, 2006) (excluding expert’s assessment of risk associated with environmental contamination in part because it “was performed by using only a limited number of the available samples, and those that would tend to magnify greatly the risk calculation”).

Dr. Godleski’s opinions are also unreliable because he samples non-ovarian tissue where convenient. For example, Dr. Godleski conceded at his deposition

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<sup>49</sup> (3/28/24 Godleski Dep. 182:12-22.)

that, according to Ms. Judkins' pathology report, the only location in which she was determined to have cancer was her right ovary and fallopian tube.<sup>50</sup> Yet, a majority of the alleged talc particles Dr. Godleski purports to have found were in slides taken from her left ovary and a small amount of alleged talc particles were found in her cervix and right pelvic lymph nodes.<sup>51</sup> The same is true for his findings regarding Ms. Rausa and Ms. Converse. For Ms. Rausa, the alleged talc particles were found in her lymph nodes and for Ms. Converse the alleged talc particles were found in her lymph nodes and cervix—but neither plaintiff had cancer cells in the lymph nodes or cervix—and neither had alleged talc particles in her ovarian tissue.<sup>52</sup>

**Third**, Dr. Godleski has no real way to confirm that what he reviewed was even talc in the first place. Dr. Godleski identifies talc if he finds birefringent particles that meet the magnesium and silicon atomic weight percentage ratio for talc.<sup>53</sup> As Dr. Godleski acknowledged, however, birefringent material is not necessarily talc,<sup>54</sup> and he cannot cite any authority that supports his conclusion that

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<sup>50</sup> (*Id.* 209:22-25.)

<sup>51</sup> (Godleski *Judkins* Rep. at 3-4.)

<sup>52</sup> (Godleski *Rausa* Rep. at 4; Godleski *Converse* Rep. at 4.)

<sup>53</sup> (Godleski *Converse* Rep. at 3-4.)

<sup>54</sup> (3/28/24 Godleski Dep. 53:3-9 (Q. "We talked before that components of dirt and dust are birefringent; correct?" A. "Can be."), 135:7-12.)

he can identify birefringent materials as talc as long as there is an expected ratio of magnesium to silicon within a certain range of error.<sup>55</sup> Nevertheless, when he finds birefringent material that meets his homespun criteria, he concludes that he has found talc. As such, there is no basis for Dr. Godleski's conclusion that he found *any* talc in any plaintiff's tissue.

**Fourth**, Dr. Godleski's opinions should also be excluded because he never considers the possibility that any of the other foreign particles he reportedly observed in plaintiffs' tissue samples caused their ovarian cancer. *See, e.g., Magistrini v. One Hour Martinizing Dry Cleaning*, 180 F. Supp. 2d 584, 609 (D.N.J. 2002) (excluding plaintiff's expert because "an expert is not required to rule out all alternative possible causes of a plaintiff's disease" but "'where a defendant points to a plausible alternative cause and the doctor offers no reasonable explanation' for why he still concludes that the chemical was a substantial factor in bringing about the plaintiff's disease, 'that doctor's methodology is unreliable'") (citation omitted), *aff'd*, 68 F. App'x 356 (3d Cir. 2003); *Soldo*, 244 F. Supp. 2d at 567 (excluding plaintiff's expert despite performing a differential diagnosis because it "does not reliably rule out reasonable alternative causes of ICH (such as the postpartum period) or idiopathic causes").

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<sup>55</sup> (See 3/29/24 Godleski Dep. 72:8-16.)

According to Dr. Godleski, each of the plaintiffs' tissue samples that he examined contained several foreign particles that were *not* purportedly talc particles.<sup>56</sup> Yet, Dr. Godleski made no attempt to identify any of those particles, determine whether they were carcinogens and consider whether those particles, rather than the few particles identified as talc, were the cause of any plaintiff's ovarian cancer.

For all of these reasons, Dr. Godleski's specific causation opinions are scientifically unreliable and should be excluded.

**II. DR. GODLESKI'S OPINIONS ARE INADMISSIBLE BECAUSE THEY CANNOT BE TIED TO ANY PLAINTIFF'S THEORY OF HARM.**

Each of the plaintiffs in these cases alleges that her ovarian cancer was caused by her perineal use of defendants' talcum powder products. (*See, e.g.*, Pls.' First Am. Master Long Form Compl. ¶¶ 50-51 (ECF 132).) While Dr. Godleski claims that he can identify alleged talc particles in five of these women's tissues, he admittedly *cannot* link any of the alleged talc particles he found to perineal talc use, let alone perineal use of talc from the J&J defendants. As Dr. Godleski conceded at his deposition, "there are a lot of products that have talc in them," and

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<sup>56</sup> (*See, e.g.*, Godleski *Rausa* Rep. at 4 (identifying about .3% of foreign particles, or 2 of 515, as talc); Godleski *Converse* Rep. at 4 (identifying about 1.5% of foreign particles, or 4 of 255, as talc).)

he “cannot identify the source” of the alleged talc particles he purports to find.<sup>57</sup>

That deficiency further dooms Dr. Godleski’s opinions.

For starters, Dr. Godleski ignores both the relevant literature and his own research in suggesting that the talc particles he claims to have found are from perineal talc use. As the relevant literature explains, “talc particles [are] observed to a similar extent” in the ovaries of women who were both “exposed and unexposed” to perineal talc.<sup>58</sup> While Dr. Godleski criticizes Heller 1996 as a “very flawed study,”<sup>59</sup> his certainty that the alleged talc particles he found were the result of perineal talcum powder use flies in the face of his *own* research, wherein he “had a control group of women who indicated they were not talcum powder users” but nonetheless had alleged talcum particles in their reproductive tissues.<sup>60</sup> This, too, requires exclusion of his opinions.

Finally, even if Dr. Godleski could say with any certainty that the alleged talc particles he identified in the plaintiffs’ tissue samples came from perineal talc use, he has no basis to tie them to any of defendants’ products. As Dr. Godleski

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<sup>57</sup> (3/28/24 Godleski Dep. 104:21-105:2, 108:21-23; *see also, e.g., id.* 219:20-22; 3/29/24 Godleski Dep. 150:1-4.)

<sup>58</sup> Heller, *The Relationship Between Perineal Cosmetic Talc Usage and Ovarian Talc Particle Burden*, 174(5) *Obstet. Gynecol.* 1507, 1508 (1996) (“Heller 1996”) (Ex. 13 to Davidson Decl.).

<sup>59</sup> (3/28/24 Godleski Dep. 104:21-105:2.)

<sup>60</sup> (3/29/24 Godleski Dep. 142:9-144:12.)

conceded at his deposition, there was “nothing distinctive” about the alleged talc he found in the five women’s tissues that could tie it to a particular manufacturer. Moreover, Dr. Godleski does not even have any knowledge about any plaintiff’s talc use in the first place or whether it was limited to defendants’ products.<sup>61</sup> For this reason, too, his opinions should be excluded from trial. *See Buzzerd*, 397 F. App’x at 800 (opinion that did “not fit the central question at issue in the case” was properly excluded); *Elcock v. Kmart Corp.*, 233 F.3d 734, 756 n.3 (3d Cir. 2000) (expert testimony “based on [factual] assumptions not present in the plaintiff’s case cannot be said to ‘assist the trier of fact’” because this would “mislead[] the factfinder and arguably does not comply with the ‘fit’ requirement.”) (citation omitted).

### **CONCLUSION**

For the foregoing reasons, defendants respectfully request that the Court exclude Dr. Godleski’s testimony from trial.

Dated: July 23, 2024

Respectfully submitted,

/s/ Susan M. Sharko

Susan M. Sharko

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<sup>61</sup> (See 3/28/24 Godleski Dep. 166:24-167:5, 167:8-23, 105:21-106:6, 108:17-109:7, 218:16-219:8, 219:20-22; 3/29/24 Godleski Dep. 77:20-78:1, 82:2-6, 147:21-148:5.)



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